RECEIVED
CENTRAL FAX CENTER
FEB 14 2007

REMARKS

Claims 44-46 and 48-58 are pending. With this paper, claims 44 and 55-58 have been amended.

Allowable Subject Matter

Present claims 44-46 and 48-54 have previously been determined to be allowable by the Examiner. The present amendment to claim 44 is grammatical in nature and does change the scope of the claim or introduce new matter.

Rejections Under 35 U.S.C. 102

Claims 55-58 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Schirra et al., *J. Clin. Invest.* (1998) 101:1421-1430. Applicants respectfully traverse this rejection in light of the current amendments.

As Applicants understand the rejection, the Examiner has taken the position that the term "exendin" in claims 55-58 includes the exendin antagonist exendin (9-39). Without agreeing with the Examiner's position, Applicants have amended the claims to recite exendin-3 (SEQ ID NO:7), exendin-4 (SEQ ID NO:9) or an agonist analog of exendin-3 or exendin-4. Since Schirra et al. neither teaches nor suggests the use of exendin-3, exendin-4 or agonist analogs thereof for reducing the risk of cardiovascular or cerebrovascular events due to impaired glucose tolerance, Schirra et al. does not anticipate the amended claims. Reconsideration and withdrawal of the rejection of claims 55-58 is therefore respectfully requested.

Rejections Under 35 U.S.C. 112, First Paragraph

Claims 55-58 currently stand rejection under 35 U.S.C. 112, first paragraph. In the Office action it is alleged that there is no description in the specification for a method for reducing a rick of cardiovascular event or a method for reducing a risk of cerebrovascular event by administration of a composition comprising an exendin or an exendin agonist analog.

While not agreeing with the Examiner's position, claims 55-58 have been amended to recited that the risk of a cardiovascular or cerebrovascular event is due to impaired glucose tolerance. Support for this amendment can be found throughout the specification as filed. In particular, support

for the amendment can be found at least on page 1, lines 18-20; page 1 line 31 through page 2, line 1; page 2, lines 8-9; page 4, lines 9-10; and page 13, lines 29-31. Specific language directed to the use of the methods of the invention to decrease the risk of cardiovascular and cerebrovascular events can be found at least on page 4, lines 9-10; and page 13, lines 29-31.

The use of exendin-3, exendin-4 and agonist analogs thereof, is likewise supported in the specification. To meet the written description requirement, the applicant must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Ex parte Anderson*, 21 USPQ 2d, 1241, 1249 (B.P.A.I., 1991). "The examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in [the] specification disclosure a description of the invention defined by the claims." *Ex parte Sorenson*, 3 U.S.P.Q. 2d 1462, 1463 (B.P.A.I. 1987). The specification states, beginning on page 6, line 31 and extending to page 7, line 2, that molecules useful in the invention include those that activate the GLP-1 receptor or a GLP-1 receptor binding compound comprising a chemically constructed molecule, peptide analogs or agonists of GLP-1. At page 7, lines 23-25 it is further stated that "[g]lucagon-like peptides and analogs will include species having insulinotropic activity and that are agonists of, i.e. activate, the GLP-1 receptor molecules and its second messenger activity on, *inter alia,* insulin producing β-cells." On page 8 the specification states that embodiments of the invention include the use of polypeptide substantially homologous to glucagon-like peptides. On page 10, exendins are specifically identified as homologous to GLP-1.

At the time of filing it was known in the art the exendins, and in particular exendin-3 and exendin-4, are insulinotropic and bind to and activate the GLP-1 receptor. See, e.g. Thorens et al., *Diabetes* (1993) 42:1678-1682). Likewise, at the time of filing, exendin peptide agonists were also known in the art, see e.g. WO 99/07404, WO 99/25727 and WO 99/25728. The Federal Circuit has held that when sequences for biological macromolecules are available in the accessible literature, satisfaction of the written description requirement does not require either recitation or incorporation by reference of such sequences. *Falkner v. Inglis*, 448 F.3d 1357, 1368 (Fed. Cir. 2006); see also *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005). The holdings in *Falkner* and *Capon* are consistent with long standing precedent "that the disclosure of an application embraces not only what is expressly set forth in words or drawings, but what would be understood by persons skilled in the art." *In re Howarth*, 654 F.2d 103, 106 (C.C.P.A. 1981); see also *Webster Loom Co. v Higgins*, 105 U.S.

RECEIVED
CENTRAL FAX CENTER
FEB 14 2007

580, 586 (1881) ("That which is common and well known is as if it were written out in the patent and delineated in the drawings."). Applicants respectfully submit that, as currently amended, claims 55-58 fully comply with the requirements of 35 U.S.C. 112, first paragraph. Reconsideration and withdrawal of the current rejection is therefore respectfully requested.

In light of the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of all rejections set forth in the Final Office Action of October 27, 2006 and the Advisory Action of January 24, 2007. Further, Applicants respectfully submit that all claims presently under consideration are in a condition for allowance and request issuance of a Notice of Allowance at the Examiner's earliest convenience.

Should the Examiner have any remaining questions regarding the subject invention or its patentability, Applicants encourage the Examiner to contact the undersigned to answer such questions or provide additional information.

PETITION FOR EXTENSION OF TIME AND AUTHORIZATION TO CHARGE FEES

Applicants hereby request an extension of time under 37 C.F.R. 1.136 for filing this paper. The Commissioner is hereby authorized to charge Deposit Account No. 010535 any fees due in association with the Request for Continued Examination and the Petition for Extension of Time. Applicants believe no additional fees are due, but if Applicants are in error, the Commissioner is hereby authorized to charge payment or credit overpayment of any due fees during the pendency of this application to Deposit Account No. 010535.

Respectfully submitted,
AMYLIN PHARMACEUTICALS, INC.

Dated: 14-Feb-07

By: _____
James E. Butler
Registration No. 40,931

AMYLIN PHARMACEUTICALS, INC.
9360 Towne Centre Drive
San Diego, CA 92121
Telephone: 858.552.2200
Facsimile: 858.552.1936